(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The netilmicin sulfate used in making the batch for potency, loss on drying, pH, residue on ignition, specific rotation, and identity.

(*b*) The batch for potency, sterility, pyrogens, and pH.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(*a*) The netilmicin sulfate used in making the batch: 12 packages, each containing approximately 500 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 12 immediate containers.

(*2*) For sterility testing: 20 immediate containers collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the product with 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 0.1 microgram of netilmicin per milliliter (estimated).

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(a) of this chapter, using a solution containing 10 milligrams of netilmicin per milliliter.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted solution.

[48 FR 18801, Apr. 26, 1983, as amended at 55 FR 11584, Mar. 29, 1990]

§ 444.262 Sisomicin sulfate injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sisomicin sulfate injection is an aqueous solution of sisomicin sulfate and one or more suitable buffers, chelating agents, and preservatives. Each milliliter contains sisomicin sulfate equivalent to 50 milligrams of sisomicin. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of sisomicin that it is represented to contain. It is sterile. It is nonpyrogenic. Its pH is not less than 2.5 and not more than 5.5. The sisomicin sulfate used conforms to the standards prescribed by § 444.62(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The sisomicin sulfate used in making the batch for potency, loss on drying, pH, residue on ignition, specific rotation, and identity.

(*b*) The batch for potency, sterility, pyrogens, and pH.

(ii) Samples required:

(*a*) The sisomicin sulfate used in making the batch: 12 packages, each containing approximately 500 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 12 vials.

(*2*) For sterility testing: 20 immediate containers collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the product with 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 0.1 microgram of sisomicin per milliliter (estimated).

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(a) of this chapter, using a solution containing 10 milligrams of sisomicin per milliliter.

(4) [Reserved]

(5) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted solution.

[46 FR 2989, Jan. 13, 1981, as amended at 50 FR 19919, May 13, 1985]